UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HOSPIRA, INC., Plaintiff, v. JANSSEN BIOTECH, INC.; NEW YORK UNIVERSITY; NYU LANGONE MEDICAL CENTER; and THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH, Defendants.	:	Civ. Action No. 14-cv-7049

HOSPIRA'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This declaratory judgment action is necessary to avoid undue delay in the marketing of an important new drug. Consistent with the very purpose of the Declaratory Judgment Act, Hospira is seeking a declaration that two of Defendants' (collectively, "Janssen's")[1] patents are invalid and, thus, cannot be used to block competition. Janssen's arguments for dismissal disregard controlling law and undisputed jurisdictional facts. They also disregard the established federal "patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2233 (2013).

Janssen first argues that Hospira's suit fails to present a justiciable controversy. This argument is baseless. Under *MedImmune, Inc. v. Genentech, Inc.*, the facts alleged here "under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007).

There is plainly a controversy. Hospira's exclusive marketing partner Celltrion has spent over $100 million dollars and devoted more than five years to develop the disputed product. And it has now filed an abbreviated biologics license application ("aBLA") with FDA on that product. The aBLA seeks FDA approval of an infliximab product that contains the precise antibody sequence subject to certain claims of the first asserted patent (the '471 patent) and is designed to compete with Janssen's own infliximab product, Remicade. That aBLA, which FDA has now accepted for review, also includes the amino acid sequence and precise treatment for Crohn's disease covered by the second asserted patent (the '396 patent). Hospira contends that both patents are invalid.

[1] The Kennedy Trust for Rheumatology Research is not joined in this motion.

There can be no question, based on undisputed facts, that Janssen will attempt to enforce its patents against Hospira. Janssen's Remicade is a "blockbuster drug" that generates billions of dollars of revenue for Janssen. Both patents-in-suit are enforceable despite ongoing reexamination proceedings on one of them. Janssen's commitment to enforcing both patents is a matter of public record. And Janssen has not granted Hospira a license or covenant not to sue. These and other undisputed jurisdictional facts firmly establish that Hospira's product was vulnerable to an infringement challenge at the time of the complaint and remains vulnerable now, which is all that is necessary for jurisdiction under *MedImmune*.

Attempting to muddy the waters, Janssen argues that its public acts and statements on patent enforcement are not directly related to this suit, and that potential FDA approval delays could intersect with patent expiration or invalidity issues in ways that might preclude an infringement action. (*E.g.*, Mem. in Supp. of Mot. to Dismiss, Dkt. 38 (hereinafter "Mot.") 1-2, 6.) These arguments cannot defeat subject matter jurisdiction under *MedImmune* on the undisputed record. And Janssen refuses to take the further step of disclaiming any right or intention to assert the relevant patents. That is not surprising. Remicade generated nearly $4 billion in worldwide sales for Johnson & Johnson in fiscal year 2013 alone, constituting a whopping 9.4% of the company's total revenues. (Compl. ¶ 24; Ex. 1 (Johnson & Johnson 10-K) at 3.)[2] Accordingly, every day that Janssen maintains its patent rights is a day it can protect its enormously lucrative patent monopoly and "put[] [Hospira] in the position of either pursuing arguably illegal behavior or abandoning that which [Hospira] claims a right to do"—namely, bring a competing product to market. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007). That is all Hospira need show for subject matter jurisdiction. *See id.*

[2] Unless stated otherwise, Ex. __ refers to an exhibit to the Declaration of Charles B. Klein, filed herewith.

Faced with a justiciable controversy, Janssen asks this Court to take the extraordinary step of declining to exercise its jurisdiction in light of the Biologics Price Competition and Innovation Act of 2009 ("Biologics Act"). But the plain terms of the Act's declaratory judgment provisions do not apply to Hospira or bar this suit. And rewriting them to do so would contravene the statute's text and history, settled interpretive principles, and Supreme Court and Federal Circuit precedent holding that "[t]here must be well-founded reasons for declining to entertain a declaratory judgment action," especially in "[t]he field of patent litigation," which "is particularly adapted to declaratory resolution." *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1355, 1357 (Fed. Cir. 2004). The Court should not allow Janssen to pretend it has no intention to sue now, only to bring its suit against Hospira shortly before it launches. The very purpose of the Declaratory Judgment Act is to provide patent certainty in this type of situation.

Janssen's last-ditch argument that Hospira's invalidity claims are too generalized to state a claim equally fails. Because the law favoring Janssen's position is at best unsettled, Janssen cannot establish that the allegations, taken as true, fail to state a claim as a matter of law. And even if the Court were to conclude that the claims suffer the Rule 8 deficiencies Janssen asserts, these deficiencies would be easily cured by an amended or supplemental complaint that provides the details Janssen seeks. Accordingly, the Court should deny Janssen's requests for dismissal pursuant to Rules 12(b)(1) and 12(b)(6).

BACKGROUND

In 2009, Hospira and Celltrion formed a co-exclusive distribution agreement for the joint development, manufacturing, regulatory approval, and marketing of Inflectra and Remsima, biosimilar versions of Janssen's patent-protected biologic infliximab product Remicade. (Compl. ¶¶ 2, 5, 6, 20.) Their investment covered the development and cloning of a cell line, method development and validation studies proving similarity to the reference drug (Remicade),

and a preclinical development program designed to meet FDA's requirements for biosimilars that included Phase I safety and efficacy pharmacokinetic, toxicological, and efficacy studies in animals, as well as global clinical Phase III trials with over 1,400 patients from 20 countries. (Compl. ¶¶ 21-23; Ex. 2 ("Park Decl.") ¶ 7.)

Together, Hospira and Celltrion have now filed ***76*** applications worldwide to sell infliximab, ***50*** of which have already been granted. (*See* Park Decl. ¶¶ 12-13.) Celltrion and Hospira currently sell infliximab pursuant to more than 20 of those approved applications, which cover a wide variety of indications. (*Id.*) For example, in September 2013, the European Commission approved Inflectra for multiple indications in the treatment of inflammatory conditions including rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and psoriasis. (Compl. ¶ 25; Ex. 3 at 4.) This approval is applicable to all European Union and European Economic Area countries. (Compl. ¶ 25; Ex. 3 at 4.)

On October 2, 2013, Celltrion filed its Investigational New Drug ("IND") application for infliximab with FDA, which the agency accepted approximately one month later. (Compl. ¶ 28.) In response to the IND and after receiving Celltrion's Phase I and III study results, FDA requested a short bridging study, which Celltrion completed in March 2014. (*Id.*) On August 8, 2014, Celltrion filed its aBLA seeking approval to market infliximab in the United States. (*Id.* ¶ 7.) Based on its experience with FDA and biosimilar regulatory approval, Celltrion expects that FDA will "approve Remsima [in] 2015." (*Id.*) That expectation is confirmed by FDA's recent and judicially-noticeable announcement that it has accepted the aBLA for review and set a disposition goal of June 8, 2015. (Ex. 4 (FDA aBLA acceptance)); *see also* Fed. R. Evid. 201.

As an authorized user of Celltrion's infliximab aBLA, Hospira may legally sell Inflectra in the United States as soon as Celltrion's application is approved. (Compl. ¶¶ 7, 29.)

ARGUMENT

I. THIS COURT HAS SUBJECT MATTER JURISDICTION OVER THIS ACTION

Janssen challenges subject matter jurisdiction on the grounds that this case does not currently present a justiciable controversy. (Mot. 8.) *MedImmune* dooms Janssen's challenge if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having": (1) "adverse legal interests" that (2) are "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. at 127 (citation omitted); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1338 (Fed. Cir. 2007) (explaining that "actual controversy" under the Declaratory Judgment Act has the "same [meaning] as an Article III case or controversy."). The facts alleged and "existing at the time" Hospira filed its complaint satisfy this two-part standard. *GAF Bldg. Mat. Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996) (citation omitted).

A. This Case Presents a Substantial Controversy Between Parties Having Adverse Legal Interests.

The parties have "adverse legal interests." *MedImmune*, 549 U.S. at 127. As long as Janssen's patents remain in force, they can be used to prevent Hospira from selling products that would cut directly into Janssen's multi-billion-dollar monopoly profits on Remicade. Janssen does not dispute this. Instead, it argues that this case fails the substantial controversy prong of *MedImmune*'s jurisdictional inquiry because Hospira has not shown that it "reasonably apprehend[s] a patent infringement lawsuit by Janssen." (Mot. 17.) This argument (which ignores factual allegations in the complaint that meet this standard, (*see* Compl. ¶¶ 32-45), misstates the law.

MedImmune approved a "more lenient" standard that "facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases." *Micron Tech., Inc. v. Mosaid*

Techs., Inc., 518 F.3d 897, 902 (Fed. Cir. 2008). Accordingly, pleading a "reasonable apprehension" of suit remains "one of many ways" to establish jurisdiction, *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc*., 527 F.3d 1278, 1291 (Fed. Cir. 2008). But it is not the only way. As Janssen's own brief concedes, (Mot. 13), Hospira can satisfy Article III by pleading that Janssen's conduct "puts [Hospira] in the position of either pursuing arguably illegal behavior or abandoning that which [it] claims a right to do." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007); *see also MedImmune*, 549 U.S. at 129; *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357-58 (Fed. Cir. 2013).

The undisputed jurisdictional facts alleged in Hospira's complaint amply satisfy this test. Hospira fears Janssen's patents based on a host of prior lawsuits, Janssen's refusal to license the patents-in-suit, and its public statements about Remicade's patent protection. Whether one says this history establishes a reasonable apprehension of an infringement suit or puts Hospira "in the position of pursuing arguably illegal behavior," the result is the same. It establishes that this case presents a substantial controversy over matters on which Janssen and Hospira are adverse.

Janssen's Prior Litigious Conduct Concerning Its Infliximab Monopoly. Janssen concedes that "[p]rior litigious conduct is one circumstance to be considered in a declaratory judgment jurisdictional inquiry [.]" (Mot. 15 (internal quotation marks omitted).) Yet it argues that the Court should ignore Janssen's lawsuits because they are not mirror images of this lawsuit. (*Id.* 15-16.) That argument fails because *any* litigation that reflects a patentee's "willingness to protect [its] technology" is relevant to the jurisdictional inquiry. *See Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (finding Article III controversy based, in part, on related trade secrets misappropriation suit); *Goodyear Tire &*

Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987) (same). And Janssen has engaged in quite a bit of litigation evidencing its "willingness to protect" its monopoly here.

Perhaps the most compelling evidence of Janssen's commitment to enforce patents aggressively to block Hospira and Celltrion from the market is the Canadian *Kennedy* case. (*See* Compl. ¶ 56.) In that ongoing suit, Janssen filed a "Counterclaim against Hospira Canada and Celltrion" seeking "[d]amages for infringement" and declarations of validity and infringement of an infliximab-related patent. (*see* Mot. 17; Compl. ¶ 56.) That should be proof enough that Janssen is thirsty to protect its blockbuster infliximab products from competition by Hospira.

Faced with this quintessential example of the parties' adversity, Janssen has two meager responses—that Hospira commenced suit, and that it did so in Canada. (Mot. 17.) Both are distinctions without differences. First, Janssen's "Hospira-started-it" defense amounts to nothing, because the suit—and especially Janssen's counterclaims—show that a present conflict exists between Hospira's desire to sell infliximab and Janssen's patent portfolio (which includes the Canadian Kennedy patent). Second, the Federal Circuit has held that litigation on a foreign patent covering similar technology "create[d] a sufficient affirmative act on the part of the patentee for declaratory judgment purposes." *See Arkema*, 706 F.3d at 1358; 5 Annotated Patent Digest § 37:49 (2014) (collecting cases); *cf. Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1331 (Fed. Cir. Mar. 11, 2014) ("[A] history of patent litigation between the same parties involving related technologies, products, and patents . . . may weigh in favor of the existence of subject matter jurisdiction . . . ."). [3] So too here.

[3] Other foreign litigation that is a matter of public record and detailed in Celltrion's complaint similarly establishes Janssen's willingness to assert its patents against the type of products at issue here. (*See* Celltrion Compl. ¶¶ 53-58.) These include Janssen's Remicade data exclusivity fight in Mexico with Celltrion, (*id.* ¶ 56), and a Peruvian case where Janssen's parent successfully blocked Celltrion from introducing its Remsima product into the market, (*id.* ¶ 57).

The U.S. suits Hospira cites in its complaint—*Centocor, Inc. v. Abbott Labs*. (Weil Decl. Ex. 10 (Dkt. 39-12)) and *Centocor, Inc. v. MedImmune, Inc*. (Weil Decl. Ex. 22 (Dkt. 39-27))—similarly establish Janssen's commitment (through actions by its predecessor Centocor) to protect patented technology involving monoclonal antibodies. Janssen tries to dodge this reality by distinguishing these cases as involving claims against different parties, or for different products or patents. (Mot. 15-16.) But, in the end, these arguments ignore that "[a] specific threat of infringement litigation by the patentee is not required to establish jurisdiction . . . ." *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (emphasis added). "Nor is it necessary that a patent holder make specific accusations against either the potential direct infringers or [a manufacturer-seller]." *Arkema*, 706 F.3d at 1357.[4] What matters is whether the U.S. suits evidence Janssen's commitment to enforcing its patents, *see Micron Tech., Inc*., 518 F.3d at 901, which they plainly do.

Refusal to License. To date, Janssen "has not been willing to accept Celltrion's request for a license to its U.S. Remicade-related patents," (Compl. ¶ 43,) nor has Janssen covenanted not to sue Hospira on the patents. These facts are undisputed evidence of a substantial patent controversy. *See, e.g.*, *Arkema*, 706 F.3d at 1358 (finding jurisdiction where patentee declined to issue covenant not to sue); *Arris Grp., Inc. v. British Telecommc'ns PLC*, 639 F.3d 1368, 1378 (Fed. Cir. 2011) (explaining that "the nature and extent of any communications between the

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[4] Janssen's focus on the fact that "MedImmune was licensed" in the second *Centocor* case, (Mot. 16), simply underscores the case for jurisdiction where, as here, such licensing is absent. *See supra*. Janssen similarly misses the mark in asserting that Celltrion's Massachusetts case does not evidence any enforcement intent. (Mot. 16.) Janssen was able to avoid infringement assertions in the Massachusetts case because it did not yet have product details from Celltrion's aBLA. *See* Mot. to Dismiss, Dkt. 16, Case No. 14-cv-11613 (D. Mass. May 23, 2014) at 8-10. Janssen will not be able to take the same ostrich-in-the-sand position here, because FDA's acceptance of the aBLA means Janssen will soon receive the application, *see* 42 U.S.C. § 262(l)(2)(A), and will have to address any alleged infringement it presents.

declaratory plaintiff and the patentee are certainly relevant factors to consider" in determining jurisdiction); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993) (holding that "a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination" of whether controversy exists), *abrogated on other grounds*, *MedImmune*, 549 U.S. 118. Janssen neither addresses these authorities nor moots this controversy by representing that it would *not* sue Hospira. (*See* Ltr. Seeking Permission to File, Dkt. 16 at 2-3; Mot. 13-17.) This fact alone should be enough to demonstrate that Janssen prefers the status quo—to hold its patent monopoly over Celltrion's and Hospira's heads for as long as possible.

Public Statements. Janssen has been far from silent about how it intends to use its patents against those whose competitive products would carve into Remicade's market share. Just a year ago, the Chief Financial Officer of Janssen's parent (Johnson & Johnson) acknowledged "the threat of biosimilars" to Remicade, but dismissed that threat as not "significant" because "Remicade . . . has patent protection . . . in the US through 2018." (Ex. 5 at 4; *see also* Ex. 6 at 8 (responding that investors should not be concerned about U.S. biosimilar competition because "the U.S. business is patent protected through 2018").) Janssen has even specifically identified Celltrion as a threat by publicly disclosing in an SEC filing that "Celltrion alleges that it will be seeking FDA approval to make and sell its own biosimilar version of REMICADE®," and that "[i]f any of the Le [*i.e.*, Janssen] patents is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®." (Ex. 7 at 4.) Finally, last year, in announcing that Janssen's Remicade had been awarded an additional period of patent protection in Europe due to pediatric exclusivity, a Johnson & Johnson spokesperson was quoted as saying that the patent extension would "stav[e] off generic competition for a further six months." (Compl. ¶ 39; Ex. 8.) Notably, the article

refers specifically to Celltrion's future infliximab product, indicating that Janssen intends to use its patents to prevent competition in Europe from Remsima/Inflectra. (*Id.*)

Janssen concedes that these statements "indicate that there are patents, believed to cover the blockbuster product Remicade, that are important to the company" and that they "might very well allow Hospira to conclude that potentially adverse patents exist." (Mot. 14.) Yet in the next sentence Janssen insists that the statements evidence no "threat of harm to Hospira." (*Id.*) That statement is not credible. Under any objective standard, and particularly when viewed in light of Janssen's litigation history and licensing refusals, Hospira would understand these statements to mean that continued pursuit of product approval and marketing would "put[] [Hospira] in the position of either pursuing arguably illegal behavior or abandoning that which [Hospira] claims a right to do." *SanDisk Corp.*, 480 F.3d at 1381. That is all *MedImmune* requires to establish the first (substantial controversy) prong of the jurisdictional inquiry. *See id.*; *Micron Tech., Inc.*, 518 F.3d at 901 (crediting patentee's "recent public statements and annual reports" as evidence of "aggressive litigation strategy" relevant to jurisdiction).

B. The Parties' Controversy Is Real and Immediate.

To satisfy the second prong of *MedImmune*—that the controversy be real and immediate—Hospira must show only that it has "meaningful[ly] prepar[ed] for making or using" a "substantially fixed" product in the U.S. *Cat Tech. LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881-82 (Fed. Cir. 2008). Hospira satisfies this burden based on undisputed facts.

In the U.S., the "fixed product" is the one described in Celltrion's aBLA, (*see* Ex. 4,) which defines precisely what product Celltrion and Hospira may market. *See* 42 U.S.C. § 262(a)(1)(A) ("No person shall introduce or deliver for introduction into interstate commerce any biological product unless—a biologics license under this subsection or subsection (k) is in effect for the biological product."); *Caraco Pharm. Labs.*, 527 F.3d at 1295 (finding dispute ripe

where "no additional facts [we]re required to determine whether [a] drug product infringes" because a "complete generic drug product . . . ha[d] been submitted to the FDA for approval"). And the preparation that has gone into the aBLA—twelve years of scientific research, regulatory effort, and commercialization planning—is certainly "meaningful."[5] Accordingly, the aBLA alone establishes that Janssen's dispute with Hospira is real and immediate.

But even without the aBLA, the undisputed factual allegations in the complaint suffice to satisfy the second prong of *MedImmune*. Going far beyond mere "preparation," Hospira and Celltrion sell infliximab in several countries, (Compl. ¶ 25; Weil Ex. 3 (Dkt. 39-5) ("Celltrion Compl.") ¶ 62; Park Decl. ¶¶ 12-13), and are thus currently marketing a "fixed and definite product" worldwide. Of course, Hospira wants to add the U.S. to that list, an undisputed fact which only strengthens the jurisdictional case. Because "there [is no] doubt that [Hospira] wishe[s] to sell some form of" infliximab, Hospira has met the jurisdictional threshold of meaningfully preparing a fixed product. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997); *Cat Tech.*, 528 F.3d at 881-82 (holding that TubeMaster had taken sufficiently significant and concrete steps by developing, though not manufacturing, two designs and four configurations of its loading technology).

[5] Celltrion began its efforts with monoclonal antibodies—of which infliximab is one—nearly 12 years ago. (Celltrion Compl. ¶ 1.) Infliximab and other candidates were selected in 2008, (*id.* ¶ 23), and Celltrion began its global clinical trials in March 2010 with 1,471 patients in 20 countries at 115 sites, including multiple Phase I and Phase III trials. (*Id.* ¶ 30; Park Decl. ¶ 7.) Since at least July 2013, Celltrion has been actively communicating with FDA about the content of its aBLA. (Celltrion Compl. ¶ 35; Park Decl. ¶ 15.) Celltrion submitted and FDA accepted Celltrion's IND application in the fall of 2013. (Celltrion Compl. ¶ 35; Park Decl. ¶ 15.) Based on FDA feedback, Celltrion was asked to provide a simple bridging study between European-sourced and U.S.-sourced Remicade—a final pharmacokinetics study. Celltrion completed that study in March 2014, (Celltrion Compl. ¶¶ 36, 61), "has established a manufacturing, marketing, and distribution infrastructure"—including plant expansion—for the purposes of launch preparation, (*id.* ¶ 63), and submitted its aBLA to FDA in August 2014. (Compl. ¶ 7.) That aBLA has now been accepted. (Ex. 4.)

Janssen's response would have this Court demand clairvoyance to satisfy the Declaratory Judgment Act. Even though Celltrion has submitted an application for approval of a specific product—a product that will be the same as the one already marketed and sold globally—Janssen pretends that the path forward is entirely uncertain. It says "there may never be a dispute under" the patents-in-suit, even though the parties are actively litigating a patent suit involving infliximab in Canada. (Mot. 11.) And it says there is "little certainty with respect to whether and when the FDA will approve Hospira's biosimilar for sale," and "also little certainty that, if approved, Hospira's marketing of the biosimilar will lead to any dispute under the [relevant] patents" because: (1) FDA approval of Hospira's product for a Crohn's disease indication (the subject of the '396 patent) is speculative, and (2) the U.S. Patent and Trademark Office ("PTO") rejection of the '471 patent's validity in reexamination proceedings may become final. (*Id*. at 11-13.) These arguments fail for several reasons.

First, all of Janssen's arguments confuse the existence of a live controversy now (which is what matters for jurisdiction over the complaint) with whether future events could moot that controversy later. *See Dey Pharma, LP v. Sunovion Pharm. Inc.*, 677 F.3d 1158, 1165 (Fed. Cir. 2012) ("there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot"). Right now, Janssen's enforcement posture "puts [Hospira] in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do," namely, proceed with approval and marketing of biosimilar infliximab. *MedImmune*, 549 U.S. at 129; *SanDisk Corp.*, 480 F.3d at 1381. Janssen's subjective speculation about the timing of FDA approval, (Mot. 9-10,) cannot overcome the well-pled factual allegations in the complaint that such approval is likely in 2015, (*see, e.g.*, Compl. ¶ 7; Celltrion Compl. ¶ 61), which accords with the June 8, 2015 goal date in FDA's

acceptance notice, (Ex. 4,) and is well within the range of expected approval periods courts have found imminent for declaratory judgment purposes. *See, e.g.*, *Glaxo, Inc.*, 110 F.3d at 1571 (finding jurisdiction where Novopharm's entry into "the U.S. market was not 'years away'"); *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276-78 (D. Mass. 2006) (finding the presence of a controversy when expected approval date was 20 to 24 months away); *see Boston Scientific Corp. v. Johnson & Johnson Inc.*, 532 F. Supp. 2d 648, 653 (D. Del. 2008) (finding jurisdiction in 2007 action when product expected to be launched in 2008); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1007 (N.D. Ill. 2001) (finding actual controversy despite FDA approval period of up to two years).

Second, Janssen's assertions regarding the timing of FDA review do not undermine jurisdiction because they concede the prospect of approval by 2016, (Mot. 9-10,) which is all that is necessary to "put[] [Hospira] in the position of either pursuing arguably illegal behavior." *See cases supra*; *see also Glaxo, Inc.*, 110 F.3d at 1571 (holding that the "systematic[] attempt[] to meet the applicable regulatory requirements" is sufficient for immediacy). Janssen's argument that the complaint does not allege "that the FDA has accepted [the infliximab] application for review" does not change this, because Janssen cites no case (and Hospira is aware of none) that requires such acceptance as a jurisdictional predicate.[6]

Third, Janssen argues that even if FDA approves the aBLA before 2016, the approval may not include the Crohn's disease indication covered by the '396 patent. (Mot. 11-12.) Again, this argument misses the point under relevant law, including Janssen's own cases. (*Id.* at 12 (citing *Matthews*).) The possibility that an application will not mirror FDA's final approval

[6] Regardless, FDA *has* now accepted the aBLA, (Ex. 4,) and Janssen's assertion that this development cannot affect jurisdiction because it must be evaluated "as of the date [Hospira] filed its complaint" exalts form over substance because the complaint can simply be supplemented or amended to add this fact today if deemed necessary (which it is not).

exists in nearly *every* biopharmaceutical patent case. Yet brand pharmaceutical companies routinely file patent infringement suits before the generic company has received even tentative FDA approval. *E.g.*, *Caraco Pharm. Labs*, 527 F.3d at 1291-92 (finding jurisdiction where brand's Orange Book actions caused delay in FDA approval of ANDA). Indeed, Hatch-Waxman all but guarantees that litigation will precede FDA approval because it requires suit within 45 days of a putative infringer's notice letter, *see id.* at 1282-83, often 30 months before FDA approval, and indications are often added or removed (or product adjustments made) while litigation is ongoing. So FDA approval (which FDA has targeted for June 2015 (*see* Ex. 4)) cannot possibly be a prerequisite to Article III jurisdiction. In any event, Janssen's hypothetical FDA rejection of an indication may never materialize. In fact, Hospira obtained approval of the Crohn's indication for its European product. (Ex. 9.) So Janssen's claims of "uncertainty" are just repackaged premature mootness arguments. *Dey, LP*, 677 F.3d at 1165 (also explaining that burden shifts to party asserting mootness). And cases like *Matthews*, (Mot. 12,) do not apply here because Janssen itself describes them as addressing situations where there "is *no* evidence a product will *ever* be used in an infringing way." (Mot. 12 (emphasis added).)

Fourth, Janssen's arguments regarding the status of the '471 patent's validity in reexamination proceedings similarly fail to undercut this Court's jurisdiction. Although the PTO's final rejection of the '471 patent's claims during reexamination strongly suggests the patent should be invalidated, the patent remains an impediment to market entry. (Mot. 12.) Even after final PTO action, unless "the Commissioner . . . issue[s] a certificate canceling the claims, they have not been finally determined to be unpatentable [and s]o long as there is a valid patent, a justiciable case or controversy exists with respect to the patent infringement action in the district court." *In re Bingo Card Minder Corp.*, 152 F.3d 941, 941 (Fed. Cir. 1998) (table)

(citing *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985) (same)); 4 Annotated Patent Digest § 25:103.50 (2014) ("[G]ranting a request for reexamination, and even rejecting all the claims in the original patent during a reexamination, does not destroy a district court's subject matter jurisdiction over the infringement action."); 35 U.S.C. § 307(a) (requiring certificate cancelling unpatentable claims). Because certificates canceling unpatentable claims cannot issue until after all appeals have been exhausted—a process that Janssen has not disclaimed and takes on average 27.8 months (*see* Ex. 10 (PTO Ex Parte Reexamination Filing Data))—the '471 patent will provide a jurisdictional basis for this suit for years to come.

For all of the foregoing reasons, this Court has jurisdiction under controlling law. And because the core facts that Hospira relies upon for jurisdiction are undisputed, there is no need for jurisdictional discovery. *See Sanderson v. Horse Cave Theatre 76*, 881 F. Supp. 2d 493, 502 (S.D.N.Y. 2012) ("On a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, the non-conclusory factual allegations in the complaint, unless contradicted by evidence, are taken as true and all reasonable inferences drawn from those factual allegations are construed in favor of the plaintiff.").

II. THE BIOLOGICS ACT DOES NOT BAR THIS SUIT

It is well settled that "[w]hen there is an actual controversy," "in the usual circumstance" the Court should hear the case. *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *abrogated on other grounds*, *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). Faced with a justiciable controversy, Janssen asks the Court to take the extraordinary step of "exercis[ing] its discretion" to decline statutory jurisdiction because this case "does not present the type of conduct that the Declaratory Judgment Act exists to protect." (Mot. 18.) But Janssen ignores the repeated cadence of controlling precedent that requires courts to facilitate the fastest route to resolve patent validity, including through exercise of the declaratory judgment remedy. That

precedent is particularly controlling here because "[t]here is a *stronger* public interest in the elimination of invalid patents than in the affirmation of a patent as valid"—especially for a drug that generates billions of dollars of revenue. *Nestier Corp. v. Menasha Corp-Lewisystems Div.*, 739 F.2d 1576, 1581 (Fed. Cir. 1984) (emphasis added).

Thus, "[t]here must be well-founded reasons for declining to entertain a declaratory judgment action," especially in "[t]he field of patent litigation," which "is particularly adapted to declaratory resolution." *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355, 1357 (Fed. Cir. 2004). Janssen attempts to manufacture such reasons here by arguing that the Biologics Act "controls the procedure for resolving any patent disputes that might exist" between the parties. (Mot. 18.) These arguments fail because the Biologics Act does not govern Hospira's conduct. *See* Part II-C *infra*. It does not prevent Hospira from suing Janssen any more than it prevents Janssen from suing Hospira. Nor, even if the Biologics Act did apply, would it prevent this suit from continuing. *See* Part II B-C *infra*. Janssen's Biologics Act argument is just an attempt to convince the Court to leave Hospira, a putative infringer, "helpless and immobile so long as [Janssen] refuse[s] to grasp the nettle and sue." *Capo*, 387 F.3d at 1357-58. As Federal Circuit precedent has long recognized, district courts abuse their discretion for putting a putative infringer in such an untenable position. *See, e.g., id.*; *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005) (reversing where district court, in dismissing suit, focused too much on the anticipatory nature of the controversy); *Minnesota Min. & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 676 (Fed. Cir. 1991) (same where declination of jurisdiction gave too much weight to pending interference proceeding and too little weight to harm of delay).

A. This Case Serves the Purposes of the Declaratory Judgment Act.

Contrary to Janssen's position, this case challenges exactly the "type of conduct the Declaratory Judgment Act" exists to address. (Mot. 18.) A suit presents such conduct where, as

here, its resolution would "provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Micron Tech. Inc*., 518 F.3d at 902 (citation omitted). Under the Declaratory Judgment Act, "competitors [a]re no longer restricted to an in terrorem choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests." *Id.* (quotations omitted); *see also Capo* and *Coyle*, *supra*. Janssen is thus left to argue for dismissal under the Biologics Act.

B. The Biologics Act Presents No Jurisdictional Bar to This Suit.

Citing 42 U.S.C. § 262(l)(9), Janssen appears to confine its Biologics Act arguments to a prudential case for declining this suit. (Mot. 18-19.) Section 262(l)(9)(A) says that "neither the reference product sponsor nor the subsection (k) applicant may . . . bring" a declaratory judgment action if certain statutory prerequisites (principally information sharing and notice of commercial marketing) are not met. As recent Supreme Court precedent confirms, that language is not jurisdictional. *See Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 166 (2010).

In *Reed*, the Court held that a Copyright Act provision stating that "*no civil action* for infringement of the copyright . . . *shall be instituted* until" certain conditions were met did *not* limit subject matter jurisdiction. 559 U.S. at 163 (emphasis added). As the Court explained:

> A statutory condition that requires a party to take some action before filing a lawsuit is not automatically a jurisdictional prerequisite to suit. Rather, the jurisdictional analysis must focus on the legal character of the requirement, which we discern[] by looking to the condition's text, context, and relevant historical treatment.

Reed, 559 U.S. at 166 (internal quotation marks and citations and footnotes omitted). Applying this analysis, the Court emphasized that it has "treated as nonjurisdictional" statutory "requirements that claimants must complete, or exhaust, before filing a lawsuit," particularly

where those requirements "impose[] a precondition to filing a claim that is not clearly labeled jurisdictional, is not located in a jurisdiction-granting provision, and admits of congressionally authorized exceptions." *Id.*

Broad "no action may be brought" language is found in the Hatch-Waxman Act, but not in the Biologics Act. *Compare* 21 U.S.C. § 355(c)(3)(D)(i)(I) *with* 42 U.S.C. § 262(l)(9)(A)-(C). The Biologics Act is more qualified—it says only that a party "may [not] bring" suit. The Second Circuit has held that "may not be brought" language is not jurisdictional because it is "not equivalent to a clear statement of Congress's intent to limit the power of the courts rather than the rights of litigants." *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 127 (2d Cir. 2011). This makes sense, because, like in *Reed*, the Biologics Act declaratory judgment limitations merely impose "precondition[s] to filing" that are "not clearly labeled jurisdictional," are "not located in a jurisdiction-granting provision," and "admit[] of" various statutory exceptions. *See* 42 U.S.C. § 262(l)(9). Following the Supreme Court's lead, this Court must avoid "interpret[ing]" the Biologics Act "as creating a jurisdictional bar when [it is] not framed as such." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1680 n.5 (2012).[7]

C. The Biologics Act Presents No Prudential or Other Barrier to This Suit.

Janssen's principal statutory argument under the Biologics Act is that Section 262(l)(9) justifies dismissal of this suit because "Hospira has not given notice of commercial marketing of

[7] Janssen refers in passing to *Sandoz v. Amgen*, No. 13-cv-2904, Dkt. 101 (N.D. Cal. Nov. 12, 2013), as support for the proposition that the Biologics Act bars Hospira's claim. Hospira contends that *Sandoz* was wrongly decided and will be reversed for all the reasons Sandoz has presented to the Federal Circuit. That said, this Court need not consider *Sandoz* because Janssen's Biologics Act arguments here do not appear to be jurisdictional, *see* Part II.B, and in any event this case presents jurisdictional facts far stronger than the (in Hospira's view jurisdictionally adequate) facts presented in *Sandoz*. *Compare Sandoz* Opening Br., No. 2014-1684 (Fed. Cir., Mar. 14, 2014) at 58-59 (discussing Sandoz's preparation and ongoing conduct of clinical studies) *with* Part I.B supra (explaining that Hospira and Celltrion have completed U.S. clinical studies and are actually selling their infliximab product abroad, and that FDA has accepted Celltrion's aBLA filing with an expected approval date of June 8, 2015).

its biosimilar drug pursuant to § 262(l)(8),” and allowing the case to proceed without satisfying this precondition would “allow a biosimilar applicant to by-pass the statutory procedure” for initiating declaratory judgment actions. (Mot. 19-20.) This argument fails for several reasons, most notably that the Biologics Act does not apply to Hospira or this lawsuit.

Section 262(l)(9) by its terms governs only suits by “subsection (k) [*i.e.*, biosimilar license] *applicants*.” 42 U.S.C. § 262(l)(9) (emphasis added); *see id.* § 262(l)(1)(A) (defining a “subsection (k) applicant” as “a person that submits an application under subsection (k)”). It is undisputed that Hospira is not itself a subsection (k) applicant. Janssen is thus forced to argue that the Court should ignore the statute’s plain text and hold that Hospira “should not be allowed to collaborate with Celltrion to avoid the mandates of the Biologics Act by filing suit as the marketing partner.” (Pre-Motion Conference Ltr., Dkt. 16, at 3.) Janssen’s departure from Section 262(l)(9)’s plain text alone should defeat its position. “When the statutory language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.” *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (quotation omitted). But even if the Court were willing to entertain Janssen’s extra-textual argument, it would not withstand scrutiny under settled interpretive principles and Act’s history and purpose.

Marketing agreements between applicants like Celltrion and entities like Hospira existed at the time the Act was passed. And other statutes—notably Hatch Waxman—contain language that broadly limits declaratory judgment filings by any entity, not just FDA “applicants.” 21 U.S.C. § 355(c)(3)(D)(i)(I) (delineating circumstances in which “no action shall be brought”). The Biologics Act does not contain such language. It limits its declaratory judgment prohibitions to “applicants” *per se*. 35 U.S.C. § 262(l)(9). Where, as here, Congress could have

easily incorporated a broader prohibition into the statute but did not do so, it is improper to read it in. *See, e.g.*, *Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 454 (2002) ("Congress wrote the statute in a manner that provides for liability only for successors in interest to *certain* signatory operators. If Congress meant to make a preenactment successor in interest like Jericol liable, it could have done so clearly and explicitly.").

Janssen offers no authority otherwise. (Mot. 19-21.) The sole case it invokes (*Rosuvastatin*) is inapposite because *Rosuvastatin* was a Hatch-Waxman case in which the FDA applicant was a closely held U.S. subsidiary acting on behalf of a foreign corporation, and it was the submitting entity that was trying to avoid infringement liability. *See In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 529 (Fed. Cir. 2012). Based on those facts, the Court held that both companies fell within the purview of Hatch-Waxman's definition of "applicant," which *unlike* the Biologics Act definition expressly encompasses "any person who submits an application . . . *and* any person who owns an approved application or abbreviated application." *Id*. (emphasis added). This case, by contrast, involves a statutory definition that is limited to the FDA subsection (k) applicant *per se*, which Janssen does not dispute is Celltrion, a company that is *not* owned or otherwise held by Hospira. Thus, neither the statutory text nor the only case Janssen cites in support of its privity argument applies here. And Janssen does not—and given the Act's text and legislative history cannot—identify any other way to make this argument.

At core, Janssen really just "objects to Hospira's attempt to avail itself of the benefits of the [Biologics Act] route to FDA approval without also following the statutory patent resolution provisions [and attendant declaratory judgment limitations]" the Act prescribes. (Mot. 21.) Such policy arguments do not justify rewriting federal statutes. *Lewis v. City of Chicago, Ill.*, 560 U.S. 205, 215 (2010) ("It is not for us to rewrite the statute so that it covers only what we think is

necessary to achieve what we think Congress really intended."). Nor does Janssen's policy argument make sense, because Hospira is not a party to the patent exchange. So Janssen and Hospira are equally positioned: neither can claim the Act's declaratory judgment bars protect each from suing the other. Allowing this suit to proceed in accordance with the Act's plain text also would *not* contravene the Act's patent exchange regime because: (1) this suit is largely confined to invalidity contentions that could moot the whole point of the patent exchange analysis; and (2) this suit comes at the end of the exclusivity period the statute presumes as a backdrop for the patent exchange process it delineates, so delaying it for the exchange process could effectively and improperly extend the statutory exclusivity period by up to a year. *See infra* at 24.

Finally, even if Hospira could be deemed a subsection (k) applicant-by-privity (a principle for which Janssen cites no authority and Hospira disagrees based on the Biologics Act's plain language), Section 262(l)(9) would provide no basis for dismissal because: (1) FDA has now accepted Celltrion's application; (2) the Act itself allows declaratory judgment suits by applicants (and on Janssen's theory, their privies) where they comply with the Act's patent exchange procedures; and (3) Janssen presents no evidence that Celltrion has not or will not continue to comply with those procedures. As relevant here, the Biologics Act requires section (k) applicants to engage the reference product sponsor in a series of patent information exchanges intended to frame any patent disputes for litigation or licensing, *see id.* § 262(l)(2)-(6), and notify the reference product sponsor 180 days before the applicant intends to engage in commercial marketing of its product, *id.* § 262(l)(8)(A). A biosimilar applicant *loses* the right to bring a declaratory judgment action only if it fails to meet those statutory conditions. *See id.* § 262(l)(9). That has not happened, and Janssen has not established that it will.

In order to avoid the Act's restrictions on declaratory judgment suits, Celltrion must: (1) timely (within 20 days of the aBLA's acceptance) provide its application and supporting information to Janssen; (2) participate in the patent list exchange; and (3) give its notice of marketing. Celltrion has expressed no reluctance to do any of these things. In fact, Celltrion has arguably already given its notice of commercial marketing by filing its Massachusetts complaint—thus defeating Janssen's main argument for declining to hear this suit. (Mot. 19.) In that complaint, Celltrion told Janssen that Celltrion was "poised to introduce Remsima® into the U.S. market immediately upon the FDA's approval of Celltrion's BLA" and that "*[t]he Remsima® product Celltrion will market in the United States* is fixed and definite." (Celltrion Compl. ¶¶ 61, 62.) These statements should satisfy the Act's notice provision, which does not prescribe any particular form. Even if they do not, Celltrion still has time to provide notice that, under Janssen's proxy theory, would constitute adequate notice from Hospira too. (Mot. 19-20.)[8]

For all of these reasons, Janssen has failed to establish—even as a matter of prudence or policy—that this suit conflicts with the Biologic Act's patent exchange provisions. If Janssen identifies additional patents during the exchange, it can assert infringement counterclaims in this litigation on these additional patents, and Hospira can amend its complaint to include them. In the meantime, allowing the suit to proceed on invalidity contentions that could moot the need for portions of the exchange advances the "significant public policy interest in removing invalid

[8] This reading of the notice requirement comports with its function: to protect the biosimilar *applicant*, not the reference product sponsor. *See* § 262(l)(8)(A). The patent exchange serves to encourage licensing and to narrow the number of patents in dispute under section 271(e). *See* § 262(l)(2)-(6). Thus, the Act gives the biosimilar applicant control of what patents appear on the final list and whether they are litigated immediately (as patents that the biosimilar applicant agrees to put on the list) or potentially litigated later (after the notice of commercial marketing). *See* § 262(l)(3)(B) & (5)(B)(i). In other words, a biosimilar applicant can decide whether to litigate only core patents early, or litigate them all at once. Here, Celltrion has opted to litigate all of patents as early as possible. This Court has no reason to upset that decision under the auspices of declaratory judgment discretion.

patents from the public arena," and the policy of the Biologics Act itself. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354 (Fed. Cir. 2005); *see Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 46 (July 14, 2009) (testimony of the Biotechnology Industry Organization) ("[A]ny legislation must include a balanced and fair procedure for identifying and resolving patent disputes . . . *before the biosimilar product is approved and put on the market*. Nearly all stakeholders agree that doing so is better for patients, caregivers, and both innovator and biosimilar companies.") (emphasis added).

By contrast, forcing Hospira to wait until the patent exchange process is complete to proceed on its invalidity claims would grant Janssen an additional exclusivity the Act does not afford. In the ordinary operation of the Biologics Act (*i.e.*, for a drug where the reference product sponsor files its BLA tomorrow), the reference product sponsor receives 12 years of exclusivity. 42 U.S.C. 262(k)(7)(A). After the first four years, a biosimilar applicant can file its own application, leaving an 8-year period for patent resolution under the Biologics Act. Yet, for drugs like infliximab that received FDA approval in the late 1990s, § 262 exclusivity has already expired. For these drugs, requiring the roughly 280-day patent information exchange process to precede litigation would give the reference drug owner a new and unwarranted 280-day exclusivity extension. That extra delay cannot be what Congress intended, especially where the exclusivity pertains to patents alleged to be invalid. *See, e.g.*, *Nestier Corp.*, 739 F.2d at 1581 ("[t]here is a *stronger* public interest in the elimination of invalid patents than in the affirmation of a patent as valid") (emphasis added).

For all the foregoing reasons, Janssen had not met its heavy burden of showing any "well-founded reason" for declining jurisdiction. Accordingly, the Court should hear this case.

III. THE COMPLAINT DOES NOT WARRANT DISMISSAL UNDER RULE 12(B)(6).

Janssen elevates form over substance and practical sense in arguing that Hospira's invalidity claims must be dismissed for failure to include details that this Court's local patent rules do not require Hospira to provide until later in the litigation. (Mot. 22-25); *see* S.D.N.Y. L. Pat. R. 6 (requiring that "not later than forty-five (45) days after service of the 'Disclosure of Asserted Claims and Infringement Contentions," the alleged infringer must "identify each item of prior art that the party contends allegedly anticipates or renders obvious each asserted claim, and any other grounds of invalidity, including any under 35 U.S.C. § 101 or § 112, or unenforceability of any of the asserted claims."). Emphasizing that pleading requirements should not be used to undermine or supersede such rules, several post-*Iqbal* decisions uphold invalidity claims identical or nearly identical to Hospira's, (Compl. ¶ 122,) under Rule 8. *See, e.g.*, *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 937-38 (N.D. Ill. 2010); *Microsoft Corp. v. Phoenix Solutions, Inc.*, 741 F. Supp. 2d 1156, 1159 (C.D. Cal. 2010); *Elan Pharma Int'l Ltd. v. Lupin Ltd.*, No. 09-cv-1008, 2010 WL 1372316, at *4 (D.N.J. Mar. 31, 2010); *Teirstein v. AGA Med. Corp.*, No. 08-cv-0014, 2009 WL 704138, at *4-5 (E.D. Tex. Mar. 16, 2009).

That is what the Court should do here. The heightened pleading standard Janssen urges for invalidity would depart from the standards in the federal rules. *See Teirstein*, 2009 WL 704138, at *4-5 ("The Federal Rules do not require Plaintiff to assert facts as to why the accused products allegedly infringe, nor to specifically list the accused products. Thus, to require Defendant to state facts as to why the '995 patent is invalid or to list invalidating prior art as Plaintiff suggests, would be to heighten the pleading standard for an invalidity counterclaim."). And the contrary cases Janssen cites, (Mot. 22-25,) at most establish a division of authority insufficient to justify dismissal of Hospira's complaint for failure to state a claim as a matter of

law. *See* Fed. R. Civ. P. 12(b)(6); *Orientview Techs. LLC v. Seven For All Mankind, LLC*, No. 13-cv-0538, 2013 WL 4016302, at *6 (S.D.N.Y. 2013) (describing division amongst courts).

That said, even if the Court were to adopt the pleading standard Janssen urges, the alleged deficiencies in Hospira's invalidity claims could easily be cured by amendment or supplement, particularly now that FDA has accepted the aBLA covering Hospira's infliximab product. Where that is the case, dismissal is improper. *See, e.g.*, *Rockwell Automation, Inc. v. Beckhoff Automation, LLC*, 2014 WL 2459604, at *11 (D. Nev. May 30, 2014) (rejecting motion to dismiss on Rule 8 grounds because plaintiff will receive invalidity contentions). Because Hospira is eager to proceed quickly, it is willing to accelerate the schedule for exchanging infringement and invalidity contentions. In fact, Hospira is so committed to speedy resolution of its claims that it intends to request leave to file an early, pre-discovery motion for summary judgment on both Janssen patents. When it does, Janssen will have more than mere contentions—it will have Hospira's argument, with more detail than any Rule 8 pleading requirement could possibly be construed to require. Hospira could even file that motion *before* Janssen has to answer. So the Court should not dismiss this suit for failure to state a claim even if it adopts the pleading standards and authority in Janssen's motion.

CONCLUSION

For all the foregoing reasons, this Court should deny all of the proffered grounds for dismissal in Janssen's motion.

Dated: October 16, 2014

Respectfully submitted,

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**pro hac vice application to be filed*

CERTIFICATE OF SERVICE

I hereby certify that on the 16th of October 2014, I served a copy of the foregoing MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS by ECF to all counsel of record.

/s/ Charles B. Klein
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